MAR 2 7 2014

510(k) Summary
pde-neo (K133719)

Submitter Name:	Hamamatsu Photonics K.K.
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Date Prepared:	March 20, 2014
Device Trade Name:	pde-neo
Device Common Name:	Fluorescent Angiographic System
Product Code:	IZI
Classification:	Fluorescent Angiography Systems have been classified as Class II according to 21 C.F.R. § 892.1600
Predicate Device:	Hamamatsu's PDE (K110480)
Device Description:	The pde-neo is an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used during plastic, micro-, reconstructive, and organ transplant surgeries. The pde-neo is intended for intraoperative visual assessment of blood vessels and related tissue perfusion by enabling surgeons to observe fluorescent images of blood vessels and related tissue perfusion. Indocyanine green (ICG) is injected intravenously into patients. Infrared light-emitting diodes (LEDs) are used to excite the fluorescence of ICG and illuminate the regions of a patient's anatomy to be observed. A charge coupled device (CCD) camera captures the fluorescent image that is used to assess the blood vessels and related tissue perfusion. The pde-neo consists of the following components: Camera Unit, Controller, and Remote Controller. The Camera Unit contains a CCD camera and LED light sources and is used either by hand or attaching it to a mechanical arm. The Controller receives the video signal of the fluorescent image from the Camera Unit and outputs the processed fluorescent image to the external video monitor and recorder. Adjustments of the fluorescent image are possible either by the Camera Unit or the Remote Controller. The proposed pde-neo differs from the cleared PDE in that:

1) The proposed pde-neo allows the user the option to visualize the outward appearance of the target area in color with no fluorescence, as compared to the predicate PDE's black-and-white fluorescence image only. The proposed pde-neo uses a color CCD, rather than the black-and-white CCD used in the predicate PDE. By changing the optical filters placed in front of the CCD device, one can switch the color image and the black-and-white fluorescence image displayed on the monitor.

2) The proposed pde-neo allows the user the option to display the fluorescence image in a pseudo-color form as compared to black-and-white (monochrome) display only with the predicate PDE. Ambient infrared light can sometimes cause the outer edges of the fluorescence image to be less clearly identifiable compared to the center of the image. Using the pseudo-color display, the intensity of the fluorescence is displayed in color (rather than brightness in the monochrome display), thereby allowing the clinician to see the outer area of the fluorescence area in a different manner.

3) The proposed pde-neo allows the clinician to observe the fluorescence image from a closer distance by adjusting the camera focus, which enables viewing of larger and smaller images, if necessary.

4) The proposed pde-neo includes six white LEDs on the front of the Camera Unit to illuminate the field of observation. During the observation of ICG fluorescence, the shadowless lamp that would otherwise illuminate the target area needs to be turned off because it contains a large amount of infrared light. Though normal overhead lights can be kept turned on, the field of observation may become dim. Since the white LED light does not interfere in the fluorescence image, it helps the clinician to observe the field with the naked eye while the shadowless lamp is turned off.

Intended Use: The pde-neo is an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used during plastic, micro-, reconstructive, and organ transplant surgeries.

Performance data: The pde-neo has been tested to support conformance with the following applicable standards:

- IEC 60601-1-2, Medical Electrical Equipment – Part 1-2: Electromagnetic Compatibility – Requirements and Tests 09/09/2008;
- IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 10/31/2005; and
- IEC 60825-1, Safety for laser products – Part 1: Equipment classification, requirements and user's guide, 1993 + A1 (1997) + A2 (2001).

Also, the following testing was completed to verify performance of the device:

- Functional testing of the camera lens was successfully completed to evaluate the angle of rotation required in order to focus the image; and

- A study of image quality was successfully completed to demonstrate that the quality of fluorescence images obtained from the predicate and proposed pde-neo devices are substantially equivalent.

Lastly, verification testing of the proposed device software was performed to demonstrate that the software operates as intended.

Substantial Equivalence: The intended use, indications for use, fundamental scientific technology, and the principles of operation of the proposed pde-neo and the predicate PDE (K110480) are the same. The pde-neo and the predicate PDE have similar technological characteristics, and the minor differences do not raise different questions of safety or efficacy, as confirmed by the information described in this submission. Both the proposed and predicate devices function as cameras, allowing surgeons to view fluorescent images of blood flow and evaluate tissue perfusion with the use of indocyanine green. Further, the pde-neo is at least as safe and effective as the predicate device. In Hamamatsu's opinion, this leads to the conclusion of substantial equivalence between the proposed pde-neo and the predicate PDE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 27, 2014

Hamamatsu Photonics K.K.
C/O Jeffrey K. Shapiro
700 13th ST, NW Suite 1200,
Washington, DC 20005

Re: K133719
Trade/Device Name: Pde-neo
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: Class II
Product Code: IZI, OWN
Dated: December 26, 2013
Received: December 27, 2013

Dear Mr. Shapiro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133719

Device Name
Pde-neo

Indications for Use *(Describe)*
The Pde-neo is an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used during plastic, micro-, reconstructive, and organ transplant surgeries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel Date: 2014.03.27 10:53:14 -04'00'